

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/28/09 has been entered.

This Office Action is in response to the Applicant's request for continued examination received 6/02/08. Claims 1-7, 9-10, 12-14 are pending. Claims 3-7, 9 and 10 are withdrawn. Claims 8, and 11 are cancelled. Claim 1 has been amended. No claims are new.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) rejection of claims 1,2, 12 and 13 over Klein et al. (U.S. Patent # 5766908, 1998) were considered but not found persuasive.

The Applicant argues that the method of making the membrane having an affinity for biomolecules is novel over the prior art because it accomplishes the final product in only two steps as opposed to the three or four steps presented in Klein et al. However, claim 1 and all dependant claims are drawn to a product and not a process. M.P.E.P. § 2113 states "product-by process claims" such as this "are not limited to the manipulations of the recited steps, only the structure implied by the steps" as cited below:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Therefore since Klein et al. is capable of producing a membrane having an affinity for biomolecules with an enzyme attached to a aldehyde linker (see repeated action below) the final product appears the same as that of the claimed invention and therefore anticipated. M.P.E.P. § 2113 states that:

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)"

"[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it

and then obtain prior art products and make physical comparisons therewith."
In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Therefore since the amendment to the claims is only to the process, the product either is or is very similar to that taught in the prior art so the anticipation rejection stands. Furthermore the obviousness rejection over Klein et al. stands since the Applicant's traverses on the same grounds as the anticipation rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 12 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Klein et al. (U.S. Patent # 5766908).

These claims are drawn to a membrane with affinity for biomolecules made by the following steps:

- (a) providing a microporous membrane;
- (b) reacting said membrane of step (a) with a reagent containing a functional group to form a functionalized membrane containing reactive functional groups on the surfaces thereof;
- (c) contacting said functionalized membrane of step (b) with a solution containing an affinity ligand to couple said ligand to said functional group to form a biologically active membrane;
- (d) washing said biologically active membrane with a washing solution containing a volatile organic compound that is miscible with said washing solution; and
- (e) drying said biologically active membrane.

The functional group of step b can be an aldehyde. Claim 12 limits that the membrane is impregnated with glycerine. Claim 13 limits that this membrane product is placed within a filtration housing with a fluid inlet and outlet.

Klein et al. teach a microporous membrane made from hydrogel or cellulose fiber that is surface modified with an affinity ligand such as a protein, antibody or cell receptor (see Abstract and Examples 1 and 2). The microporous membrane is reacted with a functional group such as an aldehyde (col 9, lines 50-60) to bind the affinity ligand to the membrane. The membrane is washed with many water miscible and volatile solvents such as acetone (Example 2) and mixtures of water and N-methylpyrrolidone (Example 6) and dried. The membrane is also soaked with a solution of water/isopropanol/glycerol (Example 5, col 16, lines 1-5). Glycerol is synonymous with glycerine or glycerin. The membrane is then centrifuged to remove only the excess glycerol after the membrane is inherently impregnated with said glycerol (col 16, lines 1-5) via this process. The membrane is formed into a column that has a defined flow rate which inherently must have an inlet and outlet (Col 12, lines 20-35).

Therefore the reference anticipates claims 1, 2, 12 and 13.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 1, 2, 12-14 over Klein et al. (U.S. Patent # 5766908) were considered but not found persuasive.

Concerning the remaining 35 U.S.C § 103 (a) rejections in the Office Action the Applicant argues that since the new limitations/amendments of the parent claim 1 overcome the teachings of Klein et al. that they in turn overcome the remaining rejections that use these references. However as detailed above the Examiner disagrees and believes that the rejection over Klein et al. is proper and in the absence of arguments to the contrary these rejections stand for the amended claims and are repeated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 12-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. as applied above to claims 1, 2, 12 and 13 and in further view of the rational outlined below.

The description and rejection of claims 1, 2, 12 and 13 are listed in the 35 U.S.C § 102(b) rejection above. Claim 14 limits that the filtration housing from claim 13 contains three membrane products.

While Klein et al. does teach a filtration housing that contains one membrane product, they do not teach three membrane products. However M.P.E.P. § 2144.06 states

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of

combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more membrane products that serve the same purpose to the filtration housing.

Also M.P.E.P. § 2144.04 VI B state:

"that mere duplication of parts has no patentable significance unless a new and unexpected result is produced"

Therefore simply adding more membrane products that serve the same purpose to the filter housing is obvious in the absence of evidence to the contrary.

Therefore the references listed above renders obvious claims 1, 2 and 12-14.

No claims are currently allowed in this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-

9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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